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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,938	04/12/2004	Chin Ying Hsiao	09395.0001-00000	4416

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EXAMINER	
NOAKES, SUZANNE MARIE	
ART UNIT	**PAPER NUMBER**
1656	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/822,938	HSIAO ET AL.	
	Examiner	Art Unit	
	Suzanne M. Noakes, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-59 and 61-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-59 and 61-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. The response filed 20 July 2006 and amendments to the specification is acknowledged. Claims 54-59 and 61-76 are pending and under examination.

Maintained Rejections/Objections

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 54-59 and 61-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The details of the rejection are recited in the previous Office action in sections 6-7.

Response to Arguments

4. Applicant's arguments filed 54-59 and 61-76 have been fully considered but they are not persuasive.

The examiner has maintained the rejection of claims 54-59 and 61-76 under 35 U.S.C. 112 1st paragraph as lacking enablement.

Applicants traverse the rejection of record stating that a specification may meet the enablement requirement even though some experimentation may be required so long as it is not undue experimentation. Furthermore, even if the experimentation is

complex, it might not be "undue" if it is routine. Applicants further state that their invention is far from complex and is in fact all routine which only requires, at best, basic and undergraduate level skills in microbiology. It is surmised that anyone who has studied the basics in microbiology can figure out how to practice their invention, by referencing for instance, Bergey's Manual, or the ATCC or the DMZ to determine the appropriate conditions for culturing and fermenting microbes. Also, one skilled in the art would be able to determine the yield of collagen is about 10% of the weight of collagen-containing tissues by weighing the material both before and after and one skilled in the art would be able to determine the presence of collagen monomers that weigh approximately 95-100 kDa by performing SDS-Page. And finally, routine screening of the appropriate microbes using these steps does not take a long time, 7-8 days from start to finish. Thus, it is concluded that when all of these arguments are considered and the Wands factors considered, there is no lack of enablement.

The examiner respectfully disagrees. The enablement requirement is clearly predicated on not imposing undue experimentation upon a skilled artisan. In the instant situation, Applicants have not given enough information for this to be the case. For claims 54-59, 61-63 and 65-67, the claims essentially state that *any* microorganism will work for fermenting collagen containing tissues in such a way so as to achieve mostly collagen containing monomers. The amount of microorganisms in existence is hard to conceive of in numbers as new ones are discovered everyday but the number is the millions. Claims 64 and 68-76 are somewhat more defined by naming an entire genus (*Bacillus*) as being capable of achieving mostly collagen monomers through the

fermentation of the microorganism in the presence collagen tissues. The specification states that the genus' *Bacillus*, *Lactobacillus* and yeast will all work, however, the working examples are all drawn to *Bacillus*. However, that is where the disclosure ceases to detail actually how Applicants achieved their invention, because a simple statement of: "A field isolate Gram (+) bacterium, belonging to the genus Bacillus, was used in the fermentation process utilized to extract collagen from the tissues." (p. 19, 1st line, 1st paragraph) is the extent of the enabling disclosure for this genus. Which isolate/species which was used in not disclosed and as stated previously, there are approximately 193 different species of *Bacillus* (see DSMZ document cited previously) and Applicants have not disclosed even a single species from this genus which they used in their claimed invention. Applicants recognize that different microogranisms produce different enzymes that this is states in the specification as on p. 4, 3rd sentence: "Microorganisms are capable of generating a wide array of molecules as end points to fermentation." In the instant case, the end point of fermentation and which enzymes are produced is the critical end point for Applicants invention because if the proper enzymes are not produced in the fermentation culture, then the collagen will not be broken down in the manner envisaged by the claimed invention. However, Applicants essentially argue that it would be routine experimentation to make a skilled artisan go through all 193 different species (at 7-8 days per experiment) and figure out which one does or does not work and that this is not undue experimentation. The 35 U.S.C. 112 1st paragraph statue specifically states: The specification shall contain a written description of the invention, and of the manner and process of making and using

it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention. [emphasis added]. It is certainly known that not every single piece of information be included in the specification for it to be enabling. Indeed, a patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). However, in the instant situation, it is not well known in the art which microorganism or which species from *Bacillus* will ferment collagen in such as way so as to achieve Applicants invention. The Examiner recognizes that the art is not complex but this does not preclude the requirement for experimentation as undue because the test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). Thus, it is concluded that the claims are not enabled by the instant disclosure.

Conclusion

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Noakes, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 7.30am to 4.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SMN
22 September 2006

JON WEBER
SUPERVISORY PATENT EXAMINER